UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ROBERT GUSTAVESEN, JOSEPH CUGINI, DEMETRA COHEN, LEE WILBURN, JACKIE CORBIN, MARY LAW and CECELIA BRATHWAITE, on behalf of themselves and all others similarly situated,	)	
Plaintiffs	)	
v.	)	
ALCON LABORATORIES, INC.; ALCON RESEARCH, LTD.; FALCON PHARMACEUTICALS, LTD.; SANDOZ, INC.; ALLERGAN, INC.; ALLERGAN USA, INC.; ALLERGAN SALES, LLC; PFIZER INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; BAUSCH AND LOMB INCORPORATED; ATON PHARMA, INC.; MERCK & CO., INC.; MERCK, SHARP & DOHME CORP.; PRASCO, LLC; and AKORN,INC.,	)	C.A. No. 1:14-11961-MLW
Defendants.	)	

MEMORANDUM AND ORDER

WOLF, D.J. September 29, 2017

Table of Contents

I. SUMMARY

Plaintiffs Cecelia Brathwaite, Demetra Cohen, Jackie Corbin, Joseph Cugini, Robert Gustavsen, Mary Law, and Lee Wilburn bring this putative class action against a group of pharmaceutical companies that either manufacture or distribute prescription eye drops: Sandoz, Inc.; Prasco, LLC; Bausch and Lomb Inc.; Akorn, Inc.; Aton Pharma Inc.; Valeant Pharmaceuticals International Inc.; Allergan USA, Inc.; Alcon Research Ltd.; Allergan, Inc.; Allergan Sales, LLC.; Merck, Sharp & Dohme Corp.; Pfizer, Inc.; Alcon Laboratories, Inc.; Falcon Pharmaceuticals Ltd.; and Merck & Co., Inc. Plaintiffs' Amended Complaint alleges that each of the defendants manufactured or distributed prescription eye drops that were intentionally designed to dispense more liquid than the human eye is capable of absorbing. As a result, medication is wasted when the excess liquid drains through consumers' tear ducts or rolls down their cheeks. According to plaintiffs, defendants package their products in this way to compel consumers to purchase medication more frequently than necessary in order to increase profits.

The defendants have filed two motions to dismiss the Amended Complaint. The first is brought by all defendants (the "Omnibus Motion"). It raises six grounds for dismissal. In essence, the Omnibus Motion argues that plaintiffs lack standing under Article III of the United States Constitution to bring this case because

they have not been harmed, plaintiffs' claims are preempted by federal statutes and regulations governing prescription drugs, and plaintiffs have failed to adequately allege their state-law claims. The second motion (the "Generic Motion") is brought by a subset of defendants who manufacture or distribute only generic drugs: Akorn, Inc.; Alcon Laboratories, Inc.; Alcon Research Ltd.; Bausch and Lomb Incorporated Pharmaceuticals Ltd.; Falcon Pharmaceuticals Ltd.; Prasco, LLC; Sandoz, LLC; and Valeant Pharmaceuticals International Inc (the "Generic Defendants"). The Generic Motion argues that plaintiffs' claims against the Generic Defendants should be dismissed because they are preempted by regulations and duties applicable solely to generic manufacturers or distributors.

Plaintiffs have filed a Motion for Leave to File Supplemental Exhibits in Opposition to Defendants' Motions to Dismiss (the "Supplemental Exhibit Motion"), which defendants oppose. The Supplemental Exhibit Motion seeks to supplement the record with additional examples of circumstances in which plaintiffs contend the Food and Drug Administration (the "FDA") has permitted changes to a sterile product's container/closure system without prior FDA approval.

The Supplemental Exhibit Motion is being denied. Most of the additional documents plaintiffs proffer may not be considered on a motion to dismiss. The others are similar to documents the court

has considered. None of the proposed exhibits would affect the court's analysis or conclusions.

For the reasons explained in this Memorandum, the Omnibus Motion is being allowed because the plaintiffs' claims are preempted. Therefore, the Generic Motion is moot.

II. PROCEDURAL HISTORY

After plaintiffs filed their original complaint, defendants filed motions to dismiss. Plaintiffs then timely filed an Amended Complaint, in which plaintiffs assert three counts against all defendants. Count I alleges violations of Massachusetts General Laws Chapter 93A ("Chapter 93A"), as well as consumer protection statutes of 16 other jurisdictions that prohibit unfair or deceptive acts and practices. Plaintiffs contend that designing eye droppers to dispense more medication than necessary is an unfair act or practice in violation of these consumer protection statutes. Counts II and III seek recovery under theories of unjust enrichment and "money had and received" under the laws of 17 states, asserting that defendants were enriched by plaintiffs having to purchase more medication than necessary.

All defendants responded to the Amended Complaint by filing the Omnibus Motion. It raises six grounds for dismissal: (1) plaintiffs do not have standing under Article III of the United States Constitution because they have not alleged a cognizable injury-in-fact; (2) plaintiffs' state-law claims are preempted by

federal law under the doctrine of "impossibility preemption" because provisions of the Food Drug and Cosmetics Act, 21 U.S.C. §355 (the "FDCA"), and FDA regulations restrict defendants from altering approved drugs; (3) plaintiffs' claims are preempted under the "obstacle preemption" doctrine because imposing tort liability would interfere with Congress's objectives in passing the FDCA; (4) plaintiffs' claim under the Massachusetts Consumer Protection Statute, Chapter 93A, fails because defendants' alleged conduct fits within a safe harbor for activity permitted by federal law, plaintiffs have failed to allege "unfair" conduct, and plaintiffs have not alleged a cognizable injury; (5) plaintiffs' unjust enrichment and "money had and received" claims fail because they are precluded by New York law and plaintiffs received the benefit of the bargain for their purchase of defendants' products; and (6) plaintiffs' claims brought under consumer protection laws of states where plaintiffs do not reside are constitutionally impermissible.

The Generic Defendants also filed the Generic Motion. It makes two arguments for dismissal: (1) plaintiffs' claims against the Generic Defendants are specifically preempted by the federal duty of "sameness" applicable to generic drug manufacturers; and (2) plaintiffs' claims against generic distributors Falcon, Sandoz, and Prasco are preempted because distributors are barred from unilaterally changing generic drugs.

The court held a hearing on the motions to dismiss. The court heard argument on two issues raised in the Omnibus Motion: plaintiffs' Article III standing, and whether plaintiffs' claims were barred by the doctrine of "impossibility preemption." The court ruled orally that plaintiffs had adequately alleged Article III standing. See Oct. 30, 2015 Hrg. Tr. at 26-30. The court reserved ruling on the remaining issues and ordered the parties to file supplemental memoranda on the issue of impossibility preemption. See id. at 73-76. The parties subsequently each filed supplemental memoranda ("Defs' Suppl. Mem." and "Pls' Suppl. Mem.").

The parties filed four additional motions after they made their supplemental submissions on the motions to dismiss. Plaintiffs filed an assented-to Motion for Protective Order governing the confidentiality of documents. The court allowed that motion and entered the protective order. See Docket No. 122. Plaintiffs also filed the Supplemental Exhibit Motion, which defendants opposed. Plaintiffs then filed a Motion for Leave to File a Reply in support of their motion to file supplemental exhibits.

III. APPLICABLE STANDARDS

A. Motions to Dismiss

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint include a "short and plain statement of the claim showing

that the pleader is entitled to relief." This pleading standard does not require "detailed factual allegations," but does require "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). A court may disregard "bald assertions, unsupportable conclusions, and opprobrious epithets." In re Citigroup, Inc., 535 F.3d 45, 52 (1st Cir. 2008); Penalbert-Roia v. Fortuno-Burset, 631 F.3d 592, 595 (1st Cir. 2011).

A motion to dismiss should be denied if a plaintiff has shown "a plausible entitlement to relief." Twombly, 550 U.S. at 559. That is, the complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. (quoting Twombly, 550 U.S. at 557).

In considering a motion to dismiss under Rule 12(b)(6), the court must "take all factual allegations as true and...draw all reasonable inferences in favor of the plaintiff." Rodriguez-Ortiz v. Marao Caribe, Inc., 490 F.3d 92, 96 (1st Cir. 2007); Maldonado

v. Fontanes, 568 F.3d 263, 266 (1st Cir. 2009). The court "neither weighs the evidence nor rules on the merits because the issue is not whether plaintiffs will ultimately prevail, but whether they are entitled to offer evidence to support their claims." Day v. Fallon Cmty. Health Plan, Inc., 917 F. Supp. 72, 75 (D. Mass. 1996).

"Under Rule 12(b)(6), the district court may properly consider only facts and documents that are part of or incorporated into the complaint." Rivera v. Centro Medico de Turabo, Inc., 575 F.3d 10, 15 (1st Cir. 2009); Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993). However, there are "narrow exceptions for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiff['s] claim; or for documents sufficiently referred to in the complaint." Watterson, 987 F.2d at 3-4. When "a complaint's factual allegations are expressly linked to -- and admittedly dependent upon -- a document (the authenticity of which is not challenged), that document effectively merges into the pleadings and the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6)." Beddall v. State Street Bank and Trust Co., 137 F.3d 12, 17 (1st Cir. 1998). When such documents contradict an allegation in the complaint, the document trumps the allegation. See Clorox Co. P.R. v. Proctor & Gamble Consumer Co., 228 F.3d 24, 32 (1st Cir. 2000)

(citing Northern Indiana Gun & Outdoor Shows, Inc. v. City of South Bend, 163 F.3d 449, 454 (7th Cir. 1998)).

When a defendant seeks dismissal based upon an affirmative defense, "the facts establishing the defense must be clear 'on the face of the plaintiff's pleadings.'" Blackstone Realty LLC v. FDIC, 244 F.3d 193, 197 (1st Cir. 2001) (quoting Aldahonda-Rivera v. Parke Davis & Co., 882 F.2d 590, 591 (1st Cir. 1989)). "Furthermore, review of the complaint, together with any other documents appropriately considered under Fed. R. Civ. P. 12(b)(6), must 'leave no doubt' that the plaintiff's action is barred by the asserted defense." Id. (quoting LaChapelle v. Berkshire Life Ins. Co., 142 F.3d 507, 508 (1st Cir. 1998)).

B. Impossibility Preemption

Impossibility preemption bars state law claims when "it is 'impossible for a private party to comply with both state and federal requirements.'" Pliva v. Mensing, 564 U.S. 604, 618 (2011) (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." Id. at 620 (citing Wyeth v. Levine, 555 U.S. 555, 573 (2009)). If a party "cannot satisfy its...duties" under a state law "without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by the federal agency, that party cannot independently satisfy those

state duties for pre-emption purposes," and the state law is preempted. Id. at 623-24.

The Supreme Court has decided a trilogy of cases concerning whether state law claims are made "impossible" by FDA regulations. In Wyeth, 555 U.S. at 559-60, the plaintiff sued a brand-name drug manufacturer under state law for having insufficient warnings on the drug label. The defendant appealed the jury verdict, arguing that the plaintiff's claim was preempted because it was impossible for the defendant to change the approved drug label without violating FDA regulations, which generally prohibit changes to a drug label before the FDA approves a supplemental application. Id. at 568-69. The Supreme Court disagreed. The Court explained that the FDA's "changes being effected" ("CBE") regulation, 21 C.F.R. §314.70(c), permits drug manufacturers to make certain changes to approved products on an interim basis by submitting a supplemental drug application without first obtaining approval for the change from the FDA. Id. at 568. The Court concluded that the CBE regulation authorized the manufacturer to strengthen the drug label's safety warnings without preapproval. Id. at 569. It noted that "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application" and to require the manufacturer to change the label back. Id. at 571. Nevertheless, the Court held that because the defendant bore the burden to show impossibility,

it was required to provide "clear evidence that the FDA would not have approved a change to [the] label." Id. at 571. Because the defendant in Wyeth had presented no such evidence, the plaintiff's state law claims were not preempted. See id.

In another section of the opinion, the Court examined the history and evolution of the FDCA, noting that despite various changes to the statute and the passage of an express preemption provision for medical devices, Congress had never preempted state laws relating to prescription drugs. See id. at 574. It reasoned that "[e]vidently, [Congress had] determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." Id. The Court concluded that "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history" and that "[i]ts silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Id. 574-75.

In 2011, the Supreme Court decided a second case, Pliva, Inc. v. Mensing, 564 U.S. 604 (2011). In that case, state tort law

required defendants, manufacturers of generic versions of a brand-name drug, to bolster warnings on their labels as they became aware of additional risks of the drugs. The Supreme Court ruled that the plaintiffs' claims were preempted by FDA regulations. The Court explained that under FDA regulations, "[a] manufacturer seeking generic drug approval...is responsible for ensuring that its warning label is the same as the brand name's" and once approved, generic drug labels must remain "the same at all times as the corresponding brand-name drug labels." Id. at 612-13 (citing 21 U.S.C. §355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7); 314.150(b)(10)). The Court also accepted the FDA's position, submitted in an amicus curiae brief of the United States, that a generic manufacturer may not invoke the CBE regulation to strengthen the warning label, explaining that the court must defer to the FDA's interpretation of its own regulations because it is not "plainly erroneous or inconsistent with the regulation." Id. at 613 (quoting Auer v. Robbins, 519 U.S. 452, 461 (1996)). Therefore, the Court concluded that "if the manufacturers had independently changed their labels to satisfy their state-law duty" without the FDA's permission, "they would have violated federal law." Id. at 618 (citing 21 C.F.R. §314.150(b)(10)).

As a result, the Court found an impermissible conflict between the state and federal regimes, even though it was "possible" that the manufacturers could have convinced the FDA to strengthen the

brand name label and to permit the generic manufacturers to comply with the state law. Id. at 620-21. The Court held, as indicated earlier, that when a party cannot satisfy a state law without first obtaining the discretionary approval of a federal agency, that state law is preempted. Id. at 624. The manufacturers were not required to prove that the FDA would have rejected a proposed label change. Id. at 620-21; see also id. at 637 (Sotomayor, J. dissenting). Therefore, proof that the FDA would have rejected an attempt to comply with state law is only required when, as in Wyeth, the regulations authorize the manufacturer to change the label first and obtain approval later.

In 2013, the Supreme Court decided the third case, Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S. Ct. 2466 (2013). The Court of Appeals for the First Circuit had affirmed a jury verdict for the plaintiff in a design defect case against a generic drug manufacturer, distinguishing Pliva by holding that the manufacturer could have chosen to stop selling the drug. See id. at 2472. The Supreme Court rejected the First Circuit's approach, stating that "pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether to avoid liability." Id. at 2477-78. The Court reasoned that "if the option of ceasing to act defeated a claim of impossibility, impossibility preemption would be all but meaningless." Id. at 2477.

The Court analyzed the New Hampshire design defect statute at issue and determined that it imposed requirements precluded by federal law. See id. at 2480 (citing Bates v. Dow Agrosciences LLC, 554 U.S. 431 (2005)). It explained that under New Hampshire's risk/utility approach to determining whether a product is "unreasonably dangerous," a drug manufacturer can only reduce the danger -- "and thus [] escape liability" -- by either redesigning the drug or increasing the warning on the label. Id. at 2474-75. The Court determined that redesigning the drug in question was not possible for two reasons. First, FDA regulations require that generic drugs have the same "active ingredients, route of administration, dosage form, strength, and labeling" as the brand-name. Id. at 2475. Therefore, any change to the drug's composition sufficient to alter its effects would make it a "new drug," and the manufacturer would have been prohibited from marketing it without submitting a New Drug Application ("NDA"). Id. Second, the drug was "chemically incapable of being redesigned." Id. at 2475. The only other option to avoid state-law liability--changing the warning label--was also impossible. As the Court explained in Pliva, generic manufacturers have a duty of "sameness" requiring the generic label to be identical to the brand-name label. See id. 2479. Therefore, the Court held the statute preempted. It explained that "state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either

altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." Id. at 2469.

Responding to the dissent, the Court explained that "federal law establishes no safe-harbor for drug companies--but it does prevent them from taking certain remedial measures. Where state law imposes a duty to take such remedial measures, it actual[ly] conflict[s] with federal law by making it impossible for a private party to comply with both state and federal requirements." Id. at 2470 (internal quotation marks and citations omitted). However, under Wyeth, plaintiffs retain state law rights of action based on failures to take actions that do not require FDA approval. See 555 U.S. at 571.

C. Obstacle Preemption

Obstacle preemption is a form of "implied preemption" which mandates that "[i]f the purpose of the act cannot otherwise be accomplished--if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect-the state law must yield to the regulation of Congress within the sphere of its delegated power." Savage v. Jones, 225 U.S. 501, 533 (1912). It occurs when "under the circumstances of [the] particular case, [the state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives

of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941); see also Geier v. Am. Honda Motor Co., 529 U.S. 861, 873 (2000).

D. Consumer Protection Statutes

Plaintiffs assert claims under multiple state consumer protection statutes that they allege are similar or identical to the Massachusetts Consumer Protection Act, Chapter 93A. Chapter 93A prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws c. 93A, § 2(a). A practice is unfair or deceptive where it: (1) is within the penumbra of some common law, statutory, or other established concept of fairness; (2) is immoral, unethical, oppressive or unscrupulous; or (3) causes substantial injury to competitors. See PMP Assocs., Inc. v. Globe Newspaper Co., 366 Mass. 593, 596 (1975); Cablevision of Boston, Inc. v. Pub. Imp. Comm'n of City of Boston, 38 F. Supp. 2d 46, 60-61 (D. Mass. 1999).

E. "Money Had and Received" and Unjust Enrichment

The elements of an unjust enrichment claim under New York law are: (1) the defendants were enriched; (2) at the plaintiffs' expense; and (3) "it is against equity and good conscience to permit [the defendants] to retain what is sought to be recovered." Mandarin Trading Ltd. v Wildenstein, 16 N.Y.3d 173, 182 (N.Y. 2011). The elements of a claim for "money had and received" are substantively the same: "(1) the defendant received money

belonging to [the] plaintiff; (2) the defendant benefited from receipt of the money; and (3) under principles of equity and good conscience, the defendant should not be permitted to keep the money." Matter of Estate of Witbeck, 666 N.Y.S.2d 315, 317 (N.Y. App. Div. 1997) (quoting 22A N.Y. Jur. 2d, Contracts, § 520, at 244); see also Maxus Leasing Grp., Inc. v. Kobelco Am., Inc., 2007 WL 655779, at *5 (N.D.N.Y. Feb. 26, 2007) ("The causes of action for unjust enrichment and money had and received are identical.").

IV. FACTUAL ALLEGATIONS

Unless otherwise indicated, the facts alleged in the Amended Complaint are as follows. Plaintiffs are all citizens of either Massachusetts or New York. A large body of scientific literature establishes that the eye can only absorb 15 microliters ("µL") of medication and that prescription eye drops should, therefore, be no larger. Any medication in excess of 15 µL leaves the eye either by rolling down the cheek or being absorbed through the tear ducts. Drop sizes that exceed 15 µL carry two negative results. First, larger drops result in wasted medication on each dose, meaning that patients consume medication faster than necessary and must refill prescriptions more often, resulting in greater costs to the consumers. Second, excess medication absorbed through the tear ducts enters the bloodstream without first being filtered by the liver, leading to the potential for increased risk of side effects.

The Amended Complaint cites scientific journal articles in support of these assertions. These citations include studies and publications in which some of the defendants participated. One study involves three scientists from defendant Alcon that concluded 16 µL drops were as effective as larger drops. See Am. Compl. ¶65. The lead researcher in this study was told by an Alcon marketing executive that the company would not change the drop size because "it would mean that patients would be able to use the bottles longer and Alcon would therefore sell less product and make less money." Id. Another study involving scientists from defendant Allergan concluded that smaller eye drops are as effective as larger ones and posed less risk of excess drug absorption. See id. ¶¶66, 71-72. Plaintiffs also quote a medical e-book from an Allergan scientist as stating that "[s]maller size drops, on the order of 15 µL, have efficacy and bioavailability equivalent to larger drops, without the waste. In fact, drops of this size are preferable, as they minimize systematic exposure and wastage." Id. ¶87. Finally, plaintiffs cite studies from defendant Allergan and defendant Merck purportedly concluding that the size of an eye dropper tip is a determining factor in the cost of medications to consumers. See id. ¶¶106-07.

Despite this research, defendants intentionally designed their eye droppers to dispense larger drops, two to three times the 15 µL size. See id. ¶90. Defendants designed their bottles in

this way to increase profits by selling more medication to consumers than they need. See id. Plaintiffs contend that nothing prevents defendants from changing the eye dropper tips to deliver smaller drops, specifically arguing that there is no physical or chemical impediment to smaller drops, see id. ¶¶128-45, and that FDA regulations do not prevent the companies from changing the dropper tips, see id. ¶¶146-62.

V. THE OMNIBUS MOTION

As explained earlier, the Omnibus Motion raises five remaining grounds for dismissal. Defendants argue, among other things, that the FDA's regulation preempts plaintiff's claims. Because defendant are correct, it is not necessary to decide the merits of the other grounds for dismissal.

In particular, impossibility preemption bars plaintiffs' claims. A verdict for plaintiffs would be a finding that state law requires defendants to design their dropper tips to dispense less solution. Specifically, plaintiffs claim that the dropper must dispense 15 µL or less at a time. See Compl. at ¶78. However, as explained below, changes to the size or shape of the dropper tip would be "major changes" requiring pre-approval from the FDA and, therefore, plaintiff's claims are preempted.

The FDA has established three "reporting categories" for changes to previously approved drug products: major, moderate, and minor. See 21 C.F.R. §314.70. All proposed "major changes" must be

submitted to the FDA "prior to distribution of the product," 21 C.F.R. §314.70(b), and any state laws mandating such a change would be preempted. See Wyeth, 555 U.S. at 571-73. "Moderate changes" may be submitted under the FDA's CBE regulation without prior approval, and "minor changes" need only be described in the manufacturer's annual report to the FDA. See id. §314.70(c)-(d). Changes in these two categories are not preempted. See Wyeth, 555 U.S. at 571.

The FDA may clarify the reporting categories with interpretive guidance. See 21 U.S.C. §356a(c)(2)(C). FDA guidance is controlling "unless plainly erroneous or inconsistent" with the statute or a regulation. Pliva, 564 U.S. at 613 (quoting Auer, 519 U.S. at 461); see also Massachusetts v. Sebelius, 2009 WL 3103850, at * 2 (D. Mass. Sept. 23, 2009). Deference is owed not only to official guidance or policies, but also to materials published with regulations. See Rucker v. Lee Holding Co., 471 F.3d 6, 12 (1st Cir. 2006) (giving deference to Department of Labor's interpretation of regulation as expressed in regulatory preamble).

Defendants' primary argument is that any change to the "container" or the "container closure system" of a "sterile drug product" is per se a "major change." See Omnibus Mem. at 12-13. "Changes that may affect drug substance or drug product sterility assurance, such as changes in drug substance, drug product, or component sterilization method(s) or an addition, deletion, or

substitution of steps in an aseptic processing operation" are major changes requiring preapproval. 21 C.F.R. §314.70(b)(2)(iii). Explanatory material published by the FDA with the most recent amendment to §314.70 interprets this regulation. See Supplements and Other Changes to an Approved Application, 69 Fed. Reg. 18728 (April 8, 2004) (hereinafter the "2004 Explanatory Material") (emphasis added). It states that for sterile products "[c]hanges in the container closure system, even if minimal, may affect the sterility assurance of the drug product and are a major change." Id. at 18745 (emphasis added). It also provides that the FDA may later "identify certain container closure system changes for sterile drug products that can be reported other than by submission of a prior approval supplement. Furthermore, an applicant could submit a comparability protocol that would allow it to implement post-approval changes in sterile container closure systems without a prior approval supplement." Id. at 18751.[1]

The FDA has also issued official guidance on the reporting categories applicable to changes to drug containers. See Guidance for Industry Changes to an Approved NDA or ANDA, 2004 WL 3199016 (April 2004) (hereinafter "2004 Guidance"). The 2004 Guidance provides that "[f]or sterile drug products, any change that may

[1] The parties have not cited, and the court has not identified, any FDA guidance establishing relevant exceptions.

affect drug product sterility assurance, such as...[c]hanges in the size and/or shape of a container for a sterile drug product" are major changes requiring preapproval. Id. at *16 (emphasis added).

The parties agree that the eye drops at issue are sterile products under FDA regulations. The parties also agree that the dropper tip is part of the products' "container closure system." See Omnibus Mem. at 12-13; Pls' Resp. at 18 n.14. The parties do not address whether the dropper tip is part of the "container," which seems to have a more limited definition than "container closure system." See 2004 Guidance at *16 (using both terms in different contexts); Guidance for Industry Container Closure Systems for Packaging Human Drugs and Biologics Chemistry, Manufacturing, and Controls Documentation, 1999 WL 33935258 (May 1999), at *2 (hereinafter the "1999 Guidance")(describing "containers (e.g., ampules, vials, bottles)" as one component of the entire "container closure system," which also includes several other elements).

In any event, dropper tips are part of the "container." The 1999 Guidance explains that opthalamic products are generally designed as a bottle with a built-in tip, often referred to as a "droptainer." Id. at *17. Moreover, as the dropper tip is a part of the bottle itself, it is within the plain meaning of the term "container." Changes to the dropper tips are "changes in the size

and/or shape of a container for a sterile drug product," 2004 Guidance at *16. They are, therefore, "major changes" under §314.70(b)(2)(iii) and the 2004 Guidance. Consistent with this, changes in the container closure system are characterized as major changes. See 2004 Explanatory Material at 18745. Thus, defendants could not, as plaintiffs demand, change the dropper tip without prior approval from the FDA. Accordingly, plaintiffs' claims that defendants should have changed the dropper tips on their FDA-approved drugs are, therefore, preempted. See Bartlett, 133 S. Ct. at 2469; Pliva, 564 U.S. at 624.

Plaintiffs argue that FDA regulations do not require all changes to the container closure systems of sterile drug products to be preapproved. In support, they submit exhibits that they argue indicate that the FDA has, on at least three occasions, permitted defendants to change their containers or container closure systems without FDA preapproval, instead relying on the CBE regulation. See Pls' Omnibus Resp. at 19-20 & n.17. In particular, plaintiffs submit three FDA approval letters and two drug labels for defendant-Allergan's product Zymar.

As explained earlier, courts may consider both "matters fairly incorporated within [the complaint] and matters susceptible to judicial notice" when considering a motion to dismiss. In re Colonial Mortgage Bankers Corp. v. Lopez-Stubbe, 324 F.3d 12, 15 (1st Cir. 2003). It is also proper for courts to consider "public

documents put into the record by both plaintiffs and defendants" when considering a motion to dismiss. Id. This rule includes material appearing on government websites. See Gent v. CUNA Mut. Ins. Soc'y, 611 F.3d 79, 84 n.5 (1st Cir. 2010)(taking "judicial notice of the relevant facts provided on the [Center for Disease Control's] website, which are "not subject to reasonable dispute." (citing Fed. R. Evid. 201(b), (f); Denius v. Dunlap, 330 F.3d 919, 926-27 (7th Cir. 2003)). Courts in the District of Massachusetts have considered information on the FDA's website subject to judicial notice and consideration on a motion to dismiss. See, e.g., In re Celexa and Lexapro Mktg. and Sales Practices Litig., 2015 WL 3751422, at *3-*4 (D. Mass. June 15, 2015); In re Ariad Pharm., Inc., 2015 WL 1321438, at *22 (D. Mass. March 24, 2015); Rock v. Lifeline Systems Co., 2014 WL 1652613, at *12 (D. Mass. Apr. 22, 2014); In re Vertex Pharmaceuticals Inc., Securities Litig., 357 F. Supp. 2d 343, 352 n.4 (D. Mass. 2005).

It is proper to consider the exhibits to plaintiffs' opposition because all of the documents were on the FDA's website.[2]

[2] In their Supplemental Exhibit Motion plaintiffs ask the court to consider additional FDA documents. That motion is being denied. Plaintiffs evidently had the proposed exhibits before filing this case subject to a protective order in another case. There appears to be no good reason for their belated effort to introduce them.

More significantly, most of the documents plaintiffs seek to submit are not public documents obtained from the FDA website, but rather are private communications, and are not relied on in the complaint. They may not be considered in deciding the motion to

However, they do not alter the court's conclusion. First, plaintiffs cite no law indicating that particular actions by an agency--as opposed to the agency's official position--are relevant to interpreting a regulation. In fact, the Supreme Court has rejected invitations to apply the standards an agency follows in practice rather than the standards it officially promulgates. See Allentown Mack Sales and Service, Inc. v. N.L.R.B., 522 U.S. 359, 372-80 (1998). Second, most of plaintiffs' exhibits do not contradict the FDA's official guidance. Two of the exhibits are letters discussing unidentified changes to the "container/closure system" for two of defendants' products. See Exs. H, I. These letters do not identify what change was made to the "container/closure system" or, most importantly, provide any

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dismiss. See Watterson, 987 F.2d at 3-4; see also Madu, Edozie & Madu, P.C. v. SocketWorks Ltd. Nigeria, 265 F.R.D. 106, 122-23 (S.D.N.Y. 2010)(holding that "a plaintiff may not shore up a deficient complaint through extrinsic documents submitted in opposition to a defendant's motion to dismiss" when the proposed exhibits are not "integral" to the complaint). The documents from the FDA's website are subject to the same analysis as those submitted previously, which the court has considered.

In any event, as explained below, the private communications plaintiffs proposes to submit, which plaintiffs argue relate to some instances in which the FDA allowed changes to defendants' container closure systems without prior approval, do not alter the court's interpretation of the regulations. Isolated actions by certain FDA officials with respect to certain drug products do not supersede the agency's official position, which is expressed in the 2004 Guidance. Cf. Allentown Mack Sales and Service, Inc. v. N.L.R.B., 522 U.S. 359, 372-80 (1998).

reason to believe that the FDA permitted a "change in the size and/or shape of a container for a sterile drug product," without preapproval. 2004 Guidance at *16.

Plaintiffs' remaining exhibits concern apparent changes to the size of the bottle for one of Allergan's products, Zymar. See Exs. E-G. These documents imply that the FDA permitted Allergan to use the CBE process to change the size of the Zymar bottle from 8 milliliters to 10 milliliters. See Ex. E (letter from FDA approving a CBE-30 change to the Zymar bottle). At most, this is evidence of the FDA's failure to follow strictly its own guidance. It does not cast doubt on the plain language of the 2004 Guidance deeming all changes to the size or shape of a sterile product's container to be major changes requiring preapproval. Therefore, plaintiffs' claims that defendants should have redesigned their dropper tips after FDA-approval are preempted by FDA regulations. See Bartlett, 133 S. Ct. at 2469; Pliva, 131 S. Ct. at 624. In light of this conclusion, the court need not address the Omnibus Motions' other impossibility preemption arguments.

The parties' initial briefing did not address whether the defendant could have avoided a conflict between state and federal duties by designing the dropper tips differently before obtaining FDA approval. The distinction is significant because the "major change" restriction only applies to "changes" made to an already-approved product and does not prevent manufacturers from

submitting differently-designed drug for approval in the first place. 21 C.F.R. §314.70(b). The court raised this issue of pre-approval design at the hearing on the motion to dismiss and the parties addressed it in the supplemental briefing.

Defendants' supplemental memorandum relies on Bartlett, 133 S. Ct. at 2469, 2477-79. Defs' Suppl. Mem. at 13-14. In Bartlett, as explained earlier, the defendant faced a conflict between violating state law and redesigning its product in violation of the federal regulation requiring generic drugs to maintain the same "active ingredients, route of administration, dosage form, strength, and labeling" as the brand-name drug. 133 S. Ct. at 2475. The First Circuit had held that the plaintiff's design defect claim was not preempted because the manufacturer could have chosen to stop selling the product and avoid the conflict. Justices Breyer and Sotomayor, in dissent, agreed that simultaneous compliance with federal and state regimes was not "impossible" because manufacturers could "remove the drug from the market, or pay compensation as a cost of doing business," 133 S. Ct. at 2491 (Sotomayor, J., dissenting); see also id. at 2481 (Breyer, J., dissenting). However, in reversing the First Circuit and rejecting the "stop-selling" analysis, the majority concluded that preemption "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." 133 S. Ct. at 2470, 77.

See id. at 2477-79. It noted that "in every instance where the court has found impossibility preemption," such as Pliva, "the direct conflict between federal and state law duties could easily have been avoided if the regulated actor had simply ceased acting." Id. at 2477. The fact that no law mandated the defendants to market the drug did not alleviate the conflict they faced in doing so.

However, the plaintiff in Bartlett did not argue, as plaintiffs do in this case, that the manufacturer should have initially submitted a differently-designed product for FDA approval, before federal regulations prevented them from altering the product's design. See id. at 2491 (Sotomayor, J. dissenting)(characterizing the majority's holding as giving manufacturers a "right to continue to sell a drug free from liability once it has been approved").

In Yates v. Ortho-McNeil-Janssen Pharm., Inc., 808 F.3d 281 (6th Cir. 2015), the Sixth Circuit addressed this issue. In Yates, the Sixth Circuit held that a design defect claim was preempted even though "no federal law...restricts a brand name drug manufacturer from designing a reasonably safe product prior to FDA approval." See id. at 299-300. First, the court stated that any argument regarding a pre-approval duty is "too attenuated" because it would require the court to assume that: (1) the FDA would have approved the drug with the proposed alternative design; (2) that the plaintiff would still have used the alternative product; and

(3) that the plaintiff would not still have been harmed by the product. See id. at 299. Second, the court concluded that alleging a pre-approval duty to design a product differently was essentially the same as arguing that "defendants should never have sold the FDA-approved formulation of [the product] in the first place." Yates, 808 F.3d at 300. It held that this "never-start-selling" rationale was indistinguishable to the "stop-selling" rationale rejected in Bartlett. See id.; see also Utts v. Bristol-Myers Squibb Co., 226 F. Supp.3d 166, 185-86 (S.D.N.Y. Dec. 23, 2016); Brazil v. Janssen Research & Development LLC, 196 F. Supp.3d 1351, 1364 (N.D. Ga. 2016).

Plaintiffs' supplemental memorandum relies on Estate of Cassel v. Alza Corp, 2014 WL 856023 (W.D. Wis. March 5, 2014) to argue that claims regarding pre-approval conduct are not preempted. See Pls' Suppl. Mem. at 3-4. In Cassel, the defendant drug manufacturer cited Bartlett for its argument that the plaintiff's design defect claims were barred because the defendant could not change its product without FDA preapproval under 21 C.F.R. §314.70(b). See Cassel, 2014 WL 856023 at *4. The court rejected the defendant's contention, holding that a state law claim alleging that a product should have been designed differently prior to FDA approval is not preempted by 21 C.F.R. §314.70. See id. at *5. The court reasoned that applying preemption to these claims would "effectively foreclose all design-defect claims against drug

manufacturers, at least in systems imposing affirmative duties on manufacturers." Id.; see also Guidry v. Janssen Pharmaceuticals, 206 F. Supp. 3d 1187, 1206-07 (E.D. La. 2016), Trahan v. Sandoz, Inc. 2015 WL 2365502, at *6 (M.D. Fla. March 26, 2015), Sullivan v. Aventis, Inc., 2015 WL 4879112 (S.D.N.Y. Aug. 13, 2015). The court in Cassel concluded that precluding such claims would be incompatible with the Supreme Court's statements in Bartlett that "federal law establishes no safe-harbor for drug companies" and that the decision does not "give[] pharmaceutical companies a right to sell a federally approved drug free from common-law liability." 2014 WL 856023 at *5 (quoting 133 S. Ct. at 2378-79) (emphasis in original). Those statements were consistent with the assertion in Wyeth that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." 555 U.S. 574-75.

This court, however, finds the Sixth Circuit's conclusion in Yates more consistent with Pliva and Bartlett. As explained earlier, "the question for 'impossibility' [analysis] is whether the private party could independently do under federal law what state law requires of it." Pliva, 564 U.S. at 620 (emphasis added). When a party cannot satisfy its state-law duties without a federal agency's permission, "that party cannot independently satisfy those state duties for preemption purposes." Id. at 623-24. Therefore, in Bartlett, the Court found that marketing a redesigned

drug was "not possible" for preemption purposes in part because a differently-designed drug "would require its own NDA to be marketed in interstate commerce." 133 S. Ct. at 2475.

Federal law prohibits "any person" from "introduc[ing] or deliver[ing] for introduction into interstate commerce any new drug" if the FDA has not determined that the "probable therapeutic benefits" outweigh its "risk of harm." 21 U.S.C. §355(a); id. at 2471. Therefore, as in Bartlett, defendants here could not have marketed droppers that complied with state consumer protection and unjust enrichment laws in the manner plaintiffs advocate without the FDA's prior approval. It is irrelevant that the defendants could have designed an entirely different product before they sought approval, which may never have been granted. See Yates, 808 F.3d at 299. Therefore, the court concludes that plaintiff's claims are preempted.

This conclusion does not establish a "safe-harbor," Bartlett, 133 S. Ct. at 2470, shielding FDA-approved drugs from state-law liability. State claims are still available to challenge brand name manufacturers' failures to warn adequately of a drug's risks, Wyeth, 555 U.S. at 571, or failures to make "moderate" or "minor" changes to a product's design that would, for example, avoid deceiving consumers. See 21 C.F.R. §314.70(c)-(d). In addition, the FDA could in the future change its official position to authorize manufacturers to make certain changes to approved

products on an interim basis without preapproval, as the CBE regulation already authorizes.

However, FDA regulations, as interpreted by the FDA, now prevent defendants from changing the "size and/or shape of a container for a sterile drug product" unless and until the FDA determines that its benefits outweigh any harms. 2004 Guidance at *16. The decision whether such a change should be made is, therefore, reserved for FDA, and the Supremacy Clause prohibits judges and juries from displacing or second-guessing the FDA based on the laws of Massachusetts or other states. See Eike v. Allergan, et al., 850 F. 3d 315, 318 (7th Cir. 2017)(Posner, J.)(stating that after "defendants' large eye drops have been approved [FDA]--in other words have been determined to be safe and effective for treatment of glaucoma," the court could not "bypass the [FDA] and make its own evaluation of the safety and efficacy of an unconventionally sized eye drop for treatment of glaucoma").

VI. THE GENERIC MOTION

Because the claims against all defendants are preempted by the FDCA and regulations enforcing it, 21 U.S.C. §355(a); 21 C.F.R. §314.70(b), the Generic Motion is moot.

VII. ORDER

In view of the foregoing, it is hereby ORDERED that:

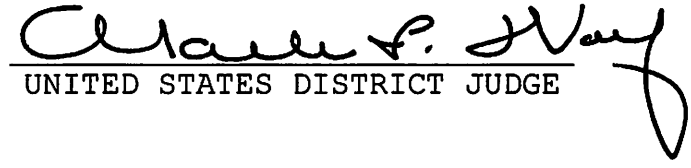
1. Defendants' Motion to Dismiss First Amended Complaint, (Docket No. 50) is ALLOWED, and this case is DISMISSED.

2. The Motion to Dismiss for Failure to State a Claim (Docket No. 52) is MOOT.

3. The Motion for Leave to File Supplemental Exhibits (Docket No. 108) is DENIED.

4. The Motion for Leave to File Reply (Docket No. 112) is ALLOWED.

5. The pending Motions for Leave to File Supplemental Authorities (Docket Nos. 133 and 135) are ALLOWED.



UNITED STATES DISTRICT JUDGE